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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/624,467

07/23/2003

Peter Berrang

BALL-13512

7442

72960

7590

02/08/2008

Casimir Jones, S.C.  
440 Science Drive  
Suite 203  
Madison, WI 53711

EXAMINER

HOPKINS, CHRISTINE D

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

02/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/624,467	<b>Applicant(s)</b> BERRANG ET AL.	
	<b>Examiner</b> CHRISTINE D. HOPKINS	<b>Art Unit</b> 3735	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4,7-9,17-19,21,27-32,43 and 45-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45-56 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7-9,17-19,21,27-32 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 January 2008 has been entered. Claims 1-2, 4, 7-9, 17-19, 21, 27-32, and 43, and 45-56 are now pending. The Examiner acknowledges the amendments to claims 1, 45, 46 and 54, as well as the cancellation of claim 44.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 4, 7, 18-19, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Leysieffer et al. (U.S. Patent No. 5,277,694). Kroll et al. (hereinafter Kroll) disclose an electromechanical transducer for an implantable hearing aid. Regarding claims 1 and 7, Kroll teaches a carrier **105**, or "housing" that is hermetically sealed, wherein the sealing has an end comprising a "wall" such that lead lines **85** and **90** enter through feedlines in

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the “wall,” and the carrier contains a “vibrational assembly” of transducer elements and inertial mass (col. 8, lines 65-67 - col. 9, lines 1-5). The transducer, or “controllable vibrating element,” may be composed of a plurality of stacked piezoelectric transducers, or piezoceramic components (col. 1, lines 51-60). The “vibrating element,” or transducer, consists of two piezoelectric elements **100A-B** (col. 8, lines 32-37), of opposite polarity whereby element transducer **100A** will expand longitudinally in response to a received electric signal and consequently, element transducer **100B** will contract longitudinally when a voltage is applied (col. 8, lines 53-61). The piezoelectric layers, stacked according to opposing polarity, may be bonded together (col. 6, lines 7-14) and may be “disk-shaped” or cylindrical (col. 12, lines 46-51). However, Kroll does not explicitly teach the composition of the bonding layers, such that the bonding layers are electrically conductive, or that a wire is attached to each of the electrically conductive bonding layers. Leysieffer et al. (hereinafter Leysieffer) discloses an electromechanical transducer for implantable hearing aids. Regarding claim 1, Leysieffer teaches a piezoelectric ceramic disk **12** having an electrically conductive coating, or “bonding layer,” which serves as an electrode. One side, or surface, is connected to ground, and the opposing electrode surface is bonded to a wire **14** which attaches to another terminal **15** (col. 7, lines 1-25). A voltage placed on both terminals results in a deflection of the piezoelectric connections, thus leading to a deviation of the metal membrane (mechanical movements) and acoustical data being transferred to the middle ear (col. 7, lines 46-51 and col. 8, lines 10-22). Kroll likewise teaches bonding of the piezoelectric elements, however does not specifically address the constituents of

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the bonding material, but similarly provides that piezoelectric transducers are useful for the amplification of audio signals into mechanical oscillations delivered to the middle ear (col. 5, lines 66-67 - col. 6, lines 1-46). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have provided an electrically conductive bonding layer to each piezoelectric element, a wire being attached to each layer as taught by Leysieffer, to a stack of piezoelectric elements of an implantable hearing device as suggested by Kroll, in order to ensure that an applied voltage sufficiently expands and contracts such piezoelectric elements for mechanical signal transduction to the middle ear of a patient.

With reference to claims 2 and 4, Kroll further discloses the device having a microphone, "electronics" for producing electrical signals, and a drive coil (col. 5, lines 36-46). An array of electrodes aids in stimulating the nerve fibers, ultimately transmitting an impulse to the brain that is interpreted as sound (col. 5, lines 5-17). Regarding claims 18-19 and 28, Kroll teaches a hermetic housing as described with reference to claim 1, having a "top" constructed of titanium (col. 8, lines 65-67), such an element having flexible properties. The "top" may be connected to a stack of piezoelectric crystals such as shown in Fig. 11A. Stacked transducers **140, 145** contain the bonded piezoelectric elements.

Regarding claim 27, "the base end" of the housing, is connected to a plurality of lead wires **85, 90** (see Fig. 7) where the lead wires are disposed through the housing "base end."

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4. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Leysieffer et al. (U.S. Patent No. 5,277,694) and further in view of Lesinski et al. (U.S. Patent No. 5,772,575). The combination of Kroll and Leysieffer discloses the invention as claimed, see rejection supra; however the combination fails to teach conductive bonding layers extending beyond the outer circumference of the piezoelectric elements. Lesinski et al. (hereinafter Lesinski) teaches a hearing device to be implanted within a subject's ear. Regarding claim 8, Lesinski discloses that conductive bonding layers (**45a** in Fig. 3) extends beyond the piezoelectric element, or transducer **45** (col. 11, lines 43-52), thus enabling it to serve as a "contact pad." Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have incorporated a conductive layer, as taught by Lesinski, extending beyond a transducer, similar to that disclosed by Kroll and Leysieffer, for providing an electrical contact for a particular element such as a lead wire or electrode.

Regarding claim 9, the combination of Kroll, Leysieffer and Lesinski discloses the invention as claimed, see rejection supra, however the combination does not expressly disclose that an etched metal clip joins the electrically conductive bonding layers. Instead, Kroll, Leysieffer and Lesinski disclose conductive bonding layers (**45a** and **45b**) formed of metallic and cermet layers (col. 11, lines 43-58 of Lesinski). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize a bent etched metal clip as the electrically conductive link because Applicant has not disclosed that utilizing a bent etched metal clip provides

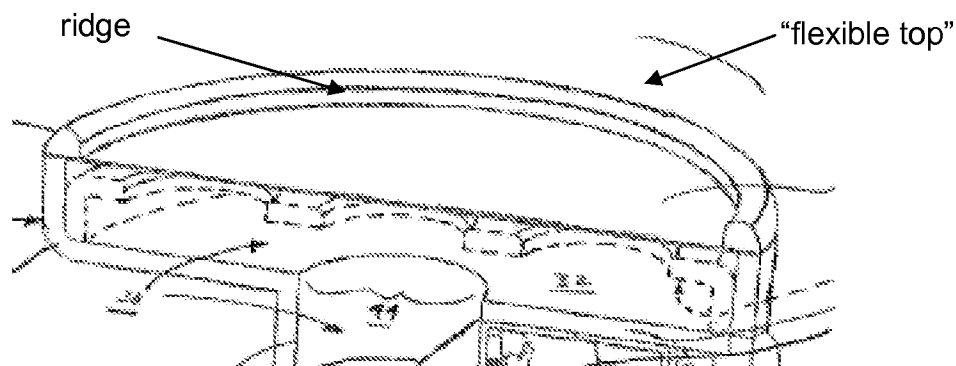
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an advantage, is used for a particular purpose, or solves a state problem. One of ordinary skill in the art, furthermore, would have expected Kroll's, Leysieffer's and Lesinski's metallic/cermet bonding layers to perform equally well with either the layers taught by Kroll, Leysieffer and Lesinski or the claimed "etched metal clip that has been bent" because both would perform the same function of electrically connecting the bonding layers. Therefore, it would have been prima facie obvious to modify the invention of Kroll, Leysieffer and Lesinski to obtain the invention as specified in claim 9 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Kroll, Leysieffer and Lesinski.

5. Claims 17 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Leysieffer et al. (U.S. Patent No. 5,277,694) and further in view of Maynard (U.S. Patent No. 6,408,496). The combination of Kroll and Leysieffer discloses the invention as claimed, see rejection supra; however the combination fails to teach a particular material used to construct the inertial mass. Maynard teaches the fabrication of a vibrational transducer suited for use in a hearing mechanism. Regarding claim 17, Maynard discloses an inertial mass composed of a dense metal such as gold or platinum (col. 6, lines 4-7). Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have made an inertial mass such as that taught by Kroll and Leysieffer of a material such as gold as disclosed by Maynard, for providing a metallic, dense element that will vibrate in response to a vibration received from a transducer within a hearing device.

Regarding claims 31-32, the housing may comprise a biocompatible coating, at least in part of silicon. Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have constructed a housing as taught by Kroll and Leysieffer, to be coated with a biocompatible material such as that disclosed by Maynard, to implant a hearing device into a particular orientation in a human ear and aid compatibility with human tissue.

6. Claims 21 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Leysieffer et al. (U.S. Patent No. 5,277,694) and further in view of Miller (U.S. Pub. No. 2002/0071585). The combination of Kroll and Leysieffer discloses the invention as claimed, see rejection supra; however the combination fails to teach a flexible top having one or more ridges in the form of concentric rings impressed into the top. Miller teaches an implantable hearing device having a microphone within a housing. Regarding claims 21 and 29-30, Miller discloses a diaphragm or “flexible top” **52** made of titanium, as in the instant application, and disk-shaped (defining a “concentric ring”) with a “ridge” or “groove” (see depiction below), having a thickness of 10 to 20 microns [0029].





Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have constructed a flexible top having the dimensions such as that taught by Miller, into a hearing device similar to that disclosed by Kroll and Leysieffer, to provide a flexible basis with a ring arrangement for a hearing device to be implanted into a particular orientation in a human ear and aid osseointegration of the device within the ear.

7. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Leysieffer et al. (U.S. Patent No. 5,277,694). The combination of Kroll and Leysieffer discloses the invention as claimed, see rejection supra, however the combination does not expressly disclose that there are between 10 and 100 of said piezoelectric elements in said stack. Instead, Kroll and Leysieffer disclose a plurality of piezoelectric elements resulting in different vibration frequency responses such that an overall frequency response bandwidth of the housing is increased (col. 11, lines 1-7). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to increase the number of piezoelectric elements in each stack because Applicant has not disclosed that inducing a hearing intensity to the implantee of up to about 120 dB by utilizing 10-100 piezoelectric elements provides an advantage, is used for a particular purpose, or solves a state problem. One of ordinary skill in the art, furthermore, would have expected Kroll's and Leysieffer's plurality of piezoelectric elements to perform equally well with either the amount taught by Kroll and Leysieffer or the claimed 10-100 piezoelectric elements because both would perform the same function of increasing the

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implantee's response to an increased frequency range. Therefore, it would have been prima facie obvious to modify Kroll and Leysieffer to obtain the invention as specified in claim 43 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Kroll and Leysieffer.

### ***Allowable Subject Matter***

8. Claims 45-56 are allowable over the prior art of record. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 45, the prior art of record does not teach or fairly suggest a hearing device having a base ring attached to a wall of a hermetic housing, a non-conductive insert attached to the base ring, and an interface element attached to at least one electrically conductive bonding layer and the non-conductive insert.

### ***Response to Arguments***

9. Applicant's arguments filed 28 January 2008 with respect to the objection to claim 54 have been fully considered and are persuasive. The objection to claim 54 has been withdrawn.

10. Applicant's arguments filed 28 January 2008 with respect to the rejection of claim 9 under 35 U.S.C. 112, second paragraph, have been fully considered and are

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persuasive. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, has been withdrawn.

11. Applicant's arguments filed 28 January 2008 with respect to the rejection of claims 1-2, 4, 7, 18, 19, 27 and 28 under 35 U.S.C. 102(b) citing Kroll ('955) have been fully considered but are moot in view of the new grounds of rejection under 35 U.S.C. 103(a) citing Kroll ('955) in view of Leysieffer ('694).

12. Applicant's arguments filed 28 January 2008 with respect to the rejection of claims 17 and 31-32 under 35 U.S.C. 103(a) citing Kroll ('955) in view of Maynard ('496) have been fully considered but are moot in view of the new grounds of rejection under 35 U.S.C. 103(a) citing Kroll ('955) in view of Leysieffer ('694) and further in view of Maynard ('496).

13. Applicant's arguments filed 28 January 2008 with respect to the rejection of claims 21 and 29-30 under 35 U.S.C. 103(a) citing Kroll ('955) in view of Miller (U.S. Pub. No. 2002/0071585) have been fully considered but are moot in view of the new grounds of rejection under 35 U.S.C. 103(a) citing Kroll ('955) in view of Leysieffer ('694) and further in view of Miller (U.S. Pub. No. 2002/0071585).

14. Applicant's arguments filed 28 January 2008 with respect to the rejection of claim 43 under 35 U.S.C. 103(a) citing Kroll ('955) have been fully considered but are moot in

view of the new grounds of rejection under 35 U.S.C. 103(a) citing Kroll ('955) in view of Leysieffer ('694).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./  
Christine D Hopkins  
Examiner  
Art Unit 3735

/Charles A. Marmor, II/  
Supervisory Patent Examiner  
Art Unit 3735